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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,764	09/24/2003	Jeffrey M. Gross	4002-3424/PC889.00	4376

7590 03/12/2007
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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT PAPER NUMBER

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/669,764

Applicant(s)

GROSS ET AL.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 18-20, 27, 29, 30, 37-40 and 43-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-17, 21-26, 28, 31-36, 41, 42 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/18/03; 8/22/05; 10/16/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 1 (claims 1-42 and 47-49 (note claim 47 has been added to this group)) and species 1 (Figures 1-2) in the reply filed on 2/23/07 is acknowledged. Applicant's traversal is on the grounds that search and examination of the entire application can be made without serious burden to the Examiner, in particular, because the searches are overlapping. Applicant's traversal has been carefully considered, but fails to establish error in the propriety of the present requirement for restriction and election.

Though Applicant asserts that examination of all pending claims would not pose an undue burden on the Examiner, such is not an accurate assertion in light of the disparate nature of the presently claimed subject matter as noted in the Requirement for Restriction; see the reasons for distinctness. Consideration of the plurality of inventions that Applicant has claimed would significantly compromise and preclude a quality examination on the merits. Furthermore, execution of a search encompassing the entirety of Applicant's claims would not only constitute an undue burden on the Examiner, but consideration of the findings of such a search in accordance with the requirements of the law under 35 U.S.C. §§101, 102, 103 and 112 would be unduly onerous.

Moreover, it is further noted that a comprehensive search for the presently claimed subject matter is not solely limited to a search of the classes and subclasses in which they are classified. Therefore, it is obvious that a comprehensive search of the

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copious amounts of patent and non-patent literature for each of the patentably distinct inventions and their permutations presently claimed would necessarily place an undue burden on the Examiner.

Regarding the election of species, the Examiner reasoning was clearly stated: "the species are independent or distinct because they have patentably distinct and mutually exclusive elements requiring different search techniques." Applicant failed to state that the species are not patentably distinct. The prosecution of the patentably distinct species places a heavy burden on the Examiner as stated above.

Therefore, for the reasons above and those made of record, the restriction requirement is deemed proper and is made FINAL.

Claims 7-9, 18-20, 27, 29, 30, 37-40, 43-46 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), as being to non-elected inventions/species are indicated by applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49, "positioning at least one member in the body extending from each of the first and second opposing sides partway toward the other opposing side" is not

understood especially with respect to the elected embodiment. The language is identical to claim 30 which is withdrawn as indicated by applicant.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the chamfered ends (claim 2) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Also:

Claim 23, fixation device allows relative motion, is not shown.

Claim 24, only a plate and screws are shown, none of the other are shown.

Please delete these from the claim.

At least claims 31 and 41, "oblique" is not shown.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant is teaching an intervertebral fusion device with fuses adjacent vertebrae. It is not enabled by the specification to use a fixation device which allows movement with a fusion device which allows for no movement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 10-12, 16, 17, 26, 28, 35, 36, 47-49 are rejected under 35 U.S.C. 102(a) as being anticipated by Germany (DE 20205016).

Germany teaches:

1. A fusion implant for insertion between adjacent bony structures, the implant comprising:

a body 1 having opposing sides for contacting the adjacent bony structures; and at least one member 3 positioned in the body, the member having a first end and a second end, the member having a tapered portion between the first and second ends.

Claim 6, "contained within the body" does not limit to not be exposed.

Claims 26 and 48, from side to side, the structural member 3 is only partway through.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-15, 21-25, 31-34, 41, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Germany (DE 20205016).

Germany teaches the fusion implant as described above, however, is silent regarding cancellous bone and cortical bone (at least claims 13-15 and 25). Germany teaches the use of synthetic materials in lieu of bone to avoid infection, etc. However, it is within the scope of the teachings and would have been obvious to one having ordinary skill in the art to have used bone (cortical and cancellous) to form the implant in any of the claimed configurations. Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make a bone fusion implant as claimed. Applicant has not disclosed that the use of bone provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the material taught by Germany or any of the materials taught by applicant.

Regarding at least claims 21-24 and 42, the use of a fixation device in combination with an intervertebral fusion device is well known in the art and would have been obvious to one having ordinary skill in the art to have used with the fusion device of Germany to better secure adjacent vertebrae.

Regarding at least claims 31 and 41, it is well known in the fusion art to have first and second surfaces which are oblique and would have been obvious to one having ordinary skill in the art to have done so with the fusion device of Germany to more closely match the oblique nature of the adjacent vertebrae.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bes

A handwritten signature in black ink, appearing to read 'Bruce Snow', with a stylized flourish extending to the right.

BRUCE SNOW
PRIMARY EXAMINER